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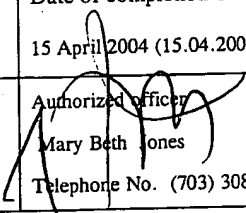
PATENT COOPERATION TREATY

PCT

DT09 Rec'd PCT/PTO 19 AUG 2004

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 2G02.2-080	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US03/05159	International filing date (day/month/year) 20 February 2003 (20.02.2003)	Priority date (day/month/year) 21 February 2002 (21.02.2002)
International Patent Classification (IPC) or national classification and IPC IPC(7): A 61 B 5/00 and US Cl.: 600/583		
Applicant FACET TECHNOLOGIES, LLC		
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>4</u> sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of ___ sheets.</p> <p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input type="checkbox"/> Non-establishment of report with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>		
Date of submission of the demand 19 September 2003 (19.09.2003)	Date of completion of this report 15 April 2004 (15.04.2004)	
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703)305-3230	Authorized officer  Mary Beth Jones Telephone No. (703) 308-0858	

Form PCT/IPEA/409 (cover sheet)(July 1998)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US03/05159**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. STATEMENT**

Novelty (N)	Claims <u>Please See Continuation Sheet</u>	YES
	Claims <u>Please See Continuation Sheet</u>	NO
Inventive Step (IS)	Claims <u>Please See Continuation Sheet</u>	YES
	Claims <u>Please See Continuation Sheet</u>	NO
Industrial Applicability (IA)	Claims <u>Please See Continuation Sheet</u>	YES
	Claims <u>Please See Continuation Sheet</u>	NO

2. CITATIONS AND EXPLANATIONS

Claims 1, 8, 9, 10, 28, 29, 33, 37-39, 48, 52, 57, 66 and 67 lack novelty under PCT Article 33(2) as being anticipated by KUHR et al.

In reference to claims 1, 8, 9, 10, 28, 29, 33, 37-39, 48, 52, 57, 66 and 67, Kuhr et al. discloses a housing (1); a cassette removably mounted in the housing, the cassette having a plurality of lancets (2) having a lancet body and a protective cap (14); a piston for propelling the lancet along a path of travel (15), the piston releasably engaging the lancet and causing separation of the lancet body and the cap (14) along at least a portion of the path of travel of the lancet. The cassette has guides (3) defining the path of travel of the lancet. Kuhr et al. discloses a carrier in the form of a circular disk (Figures 6, 7). Kuhr et al. discloses a retainer being mounted in the carrier.

Claims 21-23, 25-28, 29, 31-33, 35, 37-39, 46-55, 58 and 59 lack novelty under PCT Article 33(2) as being anticipated by SCHRAGA.

In reference to claims 21-23, 25-28, 29, 31-33, 35, 37-39, 46-55, 58 and 59, Schraga discloses at least one lancet (70) having a sharp tip and a protective cap (72) covering the sharp tip; a spring (27) for driving the lancet (70) from a first position to a second position; a cocking mechanism engaging successive lancets and arming the spring (col. 6, lines 21 - 67). Each lancet body has at least one grip flange (76) for cooperation with a cocking mechanism. Each lancet body has guide surfaces to guide the lancet for stable movement without rotation or twisting of the body. Schraga discloses a circular cassette (Figure 1) having a plurality of lancets (70) having a lancet body, tip, and protective cap (72); a carrier defining a path of travel for each lancet; and a retainer for retaining each lancet.

Claims 2-7, 11-20, 24, 30, 34, 36, 40-45, 56, 60-65 and 68 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a lancet device as claimed by applicant.

Claims 1-68 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry related to body fluid sampling.

----- NEW CITATIONS -----

NONE

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
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Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

V.1. Reasoned Statements:

The opinion as to Novelty was positive (Yes) with respect to claims 2-7, 11-20, 24, 30, 34, 36, 40-45, 56, 60-65 and 68

The opinion as to Novelty was negative (No) with respect to claims 1, 8-10, 21-23, 25-29, 31-33, 35, 37-39, 46-55, 57-59, 66 and 67

The opinion as to Inventive Step was positive (Yes) with respect to claims 2-7, 11-20, 24, 30, 34, 36, 40-45, 56, 60-65 and 68

The opinion as to Inventive Step was negative (NO) with respect to claims 1, 8-10, 21-23, 25-29, 31-33, 35, 37-39, 46-55, 57-59, 66 and 67

The opinion as to Industrial Applicability was positive (YES) with respect to claims 1-68

The opinion as to Industrial Applicability was negative (NO) with respect to claims NONE

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